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10/036,227	01/04/2002	James Norman Cawse	RD-28649	5257

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GENERAL ELECTRIC COMPANY
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EXAMINER

MAHATAN, CHANNING

ART UNIT PAPER NUMBER

1631

DATE MAILED: 04/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

SM.

Office Action Summary

Application No.

10/036,227

Applicant(s)

CAWSE, JAMES NORMAN

Examiner

Channing S Mahatan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 23-25 and 31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 and 26-30 is/are rejected.
- 7) ☒ Claim(s) 9-15, 21, 22, 26 and 30 is/are objected to.
- 8) ☒ Claim(s) 1-31 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1 Sheet.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

APPLICANT'S ELECTION

Applicant's election without traverse of Group I (claims 1-22 and 26-30; drawn to a method and system of conducting a mixture experiment) in the response filed 15 January 2004 is acknowledged.

Claims 23-25 and 31 are withdrawn from further consideration pursuant to 37 C.F.R. § 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

CLAIMS UNDER EXAMINATION

Claims herein under examination are claims 1-22 and 26-30.

INFORMATION DISCLOSURE STATEMENT

Applicant's cited reference (Conway et al.) in the 'Information Disclosure Statement', filed 04 January 2002, was lined through because a copy of the reference could not be found. Should Applicant desire consideration of the reference a copy of the reference and a newly submitted 'Information Disclosure Statement' citing the reference is requested.

CLAIM OBJECTION

Claims 9-15, 21, 22, 26, and 30 recite the abbreviation "CHTS" which is considered improper. Applicant is requested to replace "CHTS" with "combinatorial high throughput screening" as denoted in the specification (page 1, line 16) to remove confusion of abbreviation terminology.

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Claims Rejected Under 35 U.S.C. § 101

35 U.S.C. § 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-9 and 11-22 are rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter.

NON-STATUTORY SUBJECT MATTER

Claims 1-9 and 11-22 are rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter. The claimed invention is directed to a “method of conducting a mixture experiment”.

M.P.E.P. section entitled “Nonstatutory Subject Matter” (pages 2100-12, Columns 1-2) states:

Claims to processes that do nothing more than solve mathematical problems or manipulate abstract ideas or concepts are more complex to analyze and are addressed below. If the “acts” of a claimed process manipulate only numbers, abstract concepts or ideas, or signals representing any of the foregoing, the acts are not being applied to appropriate subject matter. *Schrader*, 22 F.3d at 294-95, 30 U.S.P.Q.2d at 1458-59. Thus, a process consisting solely of mathematical operations, i.e., converting one set of numbers into another set of numbers, does not manipulate appropriate subject matter and thus cannot constitute a statutory process.

Further, M.P.E.P. section entitled “Statutory Process Claims” (page 2100-15, Column 1-2) states:

A claim that requires one or more acts to be performed defines a process. However, not all processes are statutory under 35 U.S.C. 101. *Schrader*, 22 F.3d at 296, 30 U.S.P.Q.2d at 1460. To be statutory, a claimed computer-related process must either: (A) result in a physical transformation outside the computer for which a practical application in the technological arts is either disclosed in the specification or would have been known to a skilled artisan (discussed in i) below), or (B) be limited to a practical application within the technological arts (discussed in ii) below). See *Diamond v. Diehr*, 450 U.S. at 183-84, 209 U.S.P.Q. at 6 (quoting *Cochrane v. Deener*, 94 U.S. 780, 787-88 (1877)) (“A [statutory] process is a mode of treatment of certain materials to produce a given result. It is an act, or a series of acts, performed upon the subject-matter to be transformed and reduced to a different state or thing.... The process requires that certain things should be done with certain substances, and in a certain order; but the tools to be used in doing this may be of secondary consequence.”). See also *Alappat*, 33 F.3d at 1543, 31 U.S.P.Q.2d at 1556-57 (quoting *Diamond v. Diehr*, 450 U.S. at 192, 209 U.S.P.Q. at 10). See also *id.* at 1569, 31 U.S.P.Q.2d at 1578-79 (Newman, J., concurring) (“unpatentability of the principle

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does not defeat patentability of its practical applications”) (citing O ’Reilly v. Morse, 56 U.S. (15 How.) at 114-19). If a physical transformation occurs outside the computer, a disclosure that permits a skilled artisan to practice the claimed invention, i.e., to put it to a practical use, is sufficient. On the other hand, it is necessary for the claimed invention taken as a whole to produce a practical application if there is only a transformation of signals or data inside a computer or if a process merely manipulates concepts or converts one set of numbers into another.

It should be noted the step of “conducting an experiment” is considered to broadly encompass non-biological processes that are performed within a computer (i.e. *in silico* methods of conducting an experiment). Therefore, the computational steps/processes of claims 1-9 and 11-22 are “mental” processes of performing mathematical operations (manipulation of numbers) applied to a computer. For example, instant claim 1 comprises the steps of “determining an experimental space...” and “conducting an experiment...”. However, simply determining an experimental space and conducting an experiment provides no useful information; since there is no further indication of what the results from “conducting an experiment” are to mean (refer to below 35 U.S.C. § 112 2nd Paragraph Rejection). Additionally, while claim 22 recites the identification of an “improved result” it is unclear what Applicants’ regard an “improved result” to be (refer to below 35 U.S.C. § 112 2nd Paragraph Rejection). Thus, in the absence of any concrete or tangible result(s); the claims do not recite statutory subject matter.

Claims Rejected Under 35 U.S.C. § 112 1st Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 U.S.P.Q. 546 (B.P.A.I. 1986) and reiterated by the Court of Appeals in In re Wands, 8 U.S.P.Q. 2d 1400 at 1404 (C.A.F.C.

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1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a prima facie case are discussed below.

SCOPE OF ENABLEMENT

Claim 10 is rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling to “select a lead within 2.5 standard deviations of the highest calculated (mols of diphenylcarbonate/mols of primary catalyst) from the library of reactants”, does not reasonably provide enablement for all other means (i.e. criteria/parameter) to “select a lead from the library of reactants”.

The instant claim broadly embraces other means to “select a lead from the library of reactants” and therefore the claims are not commensurate in scope with the disclosure. The specification discloses Examples 1 & 2 which describes the “identification of an active and selective catalyst sample point (i.e. lead) for the production of aromatic carbonates” (pages 11-22) such that a sample point from an array (i.e. library) is selected wherein the lead has a turnover value within 2.5 standard deviations of the highest turnover value (page 14, paragraph [0047]; and page 19, paragraph [0055]), and the turnover value is calculated as mols of diphenylcarbonate/mols of primary catalyst (page 14, paragraph [0044]; and pages 18-19,

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paragraph [0052]). None of the above elements are limitations of the instant claim. No other criteria(s)/parameter(s) are disclosed to “select a lead from the library of reactants”. The specification does not provide guidance, direction, or examples for the determination of other criteria(s)/parameter(s) that define a lead and thereby utilizing said determined criteria(s)/parameter(s) for the selection of a lead from the library of reactants. Therefore, one of skill in the art would be required to perform further undue experimentation through trial and error experiments to establish criteria(s)/parameter(s) that define a lead from the numerous reactants in the library by performing various tests and validations, then utilizing these newly established selection criteria(s)/parameter(s) to select a lead from the library of reactants. Thus, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Claims Rejected Under 35 U.S.C. § 112 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-22 and 26-30 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

VAGUE AND INDEFINITE

Claims 1-9 and 11-22 are confusing with regard to a final result or goal. It is unclear if the step of “conducting an experiment” is intended to provide a result, wherein the claims as written fails to indicate an achieved final result. For instance, once the method of conducting a mixture experiment is performed, via determining an experiment space and conducting an

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experiment on the first factor sampled, what is the resultant value or goal that is obtained? What does the result mean? Clarification of the metes and bounds, via clearer claim language, is requested.

Claims 1-22 are confusing regarding inconsistent language within the claim and claims dependent therefrom, wherein the claim 1 in the preamble recites “mixture experiment” however, the body of the claim and all claims dependent therefrom recites only the language “experiment”. It is unclear if Applicants regard “mixture experiment” and “experiment” to be of universal terminology or whether such language is to be distinctly different. Clarification of the metes and bounds, via clearer claim language, is requested.

Claims 10, 12, 13, and all “effecting parallel reaction of the library to produce products”. It is unclear if Applicant regards the limitation of effecting to be equivalent to 1) performing the parallel reaction; or 2) causing some change to the parallel reaction. Clarification of the metes and bounds, via clearer claim language, is requested.

Claim 21 recites the limitation “effecting the CHTS method” which is vague and indefinite. It is unclear if Applicant regards the limitation of effecting to be equivalent to 1) performing the CHTS method; or 2) causing some change to the CHTS method. Clarification of the metes and bounds, via clearer claim language, is requested.

Claim 21 recites the phrase “essentially independent” which is confusing. Is the reaction rate independent or not? If not, what limitation is implied by the phrase “essentially independent”. Applicant is requested to clarify this issue via clearer claim language.

Claim 22 recites the limitation “an improved result” which is considered vague and indefinite. It is unclear what Applicant regards as “an improved result”, wherein no indicated

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“result” prior to “an improved result” is identified and therefore to be a reference for which another result is considered improved. Clarification of the metes and bounds, via clearer claim language, is requested.

Claim 22 recites the limitation “a smaller increment around the point of lead result” which is considered vague and indefinite. It is unclear what Applicant regard as “a smaller increment”, wherein no indicated “increment” is identified prior and therefore to be a reference for which another result is considered “smaller”. Additionally, the term “increment” implies a range of values/criteria, which is unclear. What does Applicant regard an “increment” to be? Clarification of the metes and bounds, via clearer claim language, is requested.

Claims 26-30 are indefinite due to the lack of clarity of the claim language failing to correspond with the preamble. The preamble states that it is “A system for conducting an experiment”, however, the claim fails to indicate a component(s) for “conducting an experiment”. None of the recited components (reactor or programmed controller) of the system are indicated for conducting an experiment. In such absence it is unclear what component(s) are to conduct an experiment as recited by the preamble. Clarification of the metes and bounds, via clearer claim language, is requested.

Claims 26 and 30 recite the limitations “to produce results” and “to detect results”, respectively, which is vague and indefinite. The limitation broadly encompasses any and all “results” and therefore the term “results” lacks any meaningful definition where one would not appreciate and understand the metes and bounds of what is considered to be a produced/detected result. Applicants’ can resolve this issue by particularly pointing out what the term “results” is

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intended to encompass, such that one could identify (i.e. criteria) produced/detected results.

Clarification of the metes and bounds, via clearer claim language, is requested.

MISSING ESSENTIAL STEPS

Claims 1-9 and 11-22 are rejected under 35 U.S.C. § 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See M.P.E.P. § 2172.01. Independent claim 1 (which claims 2-9 and 11-22 depend from) recites in the preamble “A method for conducting a mixture experiment” and “conducting an experiment...” as the final step. However, absent from the instant claims are steps for conducting a mixture experiment. Clarification of the claim language is requested.

EXAMINER COMMENT

Prior art relevant to the instantly claimed invention are Cong et al. (High-Throughput Synthesis and Screening of Combinatorial Heterogeneous Catalyst Libraries. Angew Chem. Int. Ed. 1999, Volume 38, Number 4, pages 483-488) and Senkan et al. (High-Throughput Testing of Heterogeneous Catalyst Libraries Using Array Microreactors and Mass Spectrometry).

Cong et al. reports the development of a systematic and integrated approach for combinatorial chemistry in heterogeneous catalysts through the catalytic oxidation of CO and the reduction of NO by metal alloy catalysts that consist of Rh, Pd, Pt, and Cu (i.e. Group VIII B metal, palladium, inorganic co-catalyst, a combination of inorganic co-catalysts; claims 16-18, 20, and 21). The authors create a 15x15x15 triangular library (i.e. experimental space) containing 120 different catalysts (page 484, left column, lines 38-43); depicted on page 483 and Figures 2-4), wherein the total factors are the 120 different catalysts (i.e. n) and the factor level is equal to 15 steps/intervals (i.e. M). Cong et al. conducts an experiment on all of the factor(s) of

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the library (i.e. A_{\min} to A_{\max}) by measurements (i.e. catalytic properties) of product and reactant concentrations of the formed catalytic mixture entities (i.e. Rh-Pt-Cu, Rh-Pd-Cu, and Rh-Pd-Pt libraries) are detected via a CO₂ laser and mass spectrometer or optical detector through capillary transfer line (page 494, left column, lines 17-37; and Figure 1) and identifying resulting catalyst mixtures that maintain significant oxidation activity (pages 485-486; Figures 2, 3, and 4).

Senkan et al. describes the high-throughput testing of heterogeneous catalyst libraries; reporting the results of testing a Pt/Pd/In library (i.e. experimental space) with 66 combinations for the catalytic dehydrogenation of cyclohexane to benzene utilizing an array microreactor to monitor the activities and selectivities of the heterogeneous catalyst library over time (page 2795, left column, lines 44-58). The reactor system movement (i.e. x, y, z framework) is controlled by a computer, wherein 1) catalytic mixtures are placed into the wells (i.e. dispensing assembly) of the microreactor; 2) the constructed catalytic library is subjected to heat and a carrier gas; and 3) the levels of reactants, products, and the carrier gas are determined (page 2796, left column, lines 13-35).

However, neither Cong et al. or Senkan et al. anticipate or suggest the instantly claimed invention because of the absence of the teaching for “conducting an experiment on the first factor sampled in a range of levels determined”/ “a lattice of points representing increments of reaction factor levels from a minimum level value to a maximum level value” “according to the relationship $(A_{\min} + (A_{\max} - A_{\min})/(n(M-1)))$ to $(A_{\max} - (A_{\max} - A_{\min})/(n(M-1)))$ ” (i.e. claim 1); and the particular range levels determined according to the relationship recited in claims 2 and 5-8.

No Claims Are Allowed.

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EXAMINER INFORMATION

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 C.F.R. § 1.6(d)). The CM1 Fax Center number is either (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Channing S. Mahatan whose telephone number is (571) 272-0717. The Examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina M. Plunkett, whose telephone number is (571) 272-0549 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

Date: *April 15, 2004*

Examiner Initials: *CSM*

Marianne P. Allen
MARIANNE P. ALLEN
PRIMARY EXAMINER
4/15/04
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